DEPARTMENT OF VETERANS AFFAIRS (VA)

Annual Report

Nonprofit Research and Education Corporations (NPC)



December 2021

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I. BACKGROUND

In 1988, Congress passed P.L. 100-322, now codified at sections 7361-66 of title 38, United States Code (U.S.C.), which permitted the Secretary of the Department of Veterans Affairs (VA) to authorize the establishment of Nonprofit Research and Education Corporations (NPC) at VA medical centers (VAMC). This laid the foundation for creation of unique partnerships to conduct VA-approved research. P.L. 100-322 allowed the establishment of private, state-chartered, nonprofit entities to provide flexible funding mechanisms for the administration of funds, other than those appropriated to VA, for the conduct of VA-approved research.

II. NPC ROLE IN SUPPORT OF VA RESEARCH AND EDUCATION

In 1999, Congress expanded the authority of NPCs to include support for VA's education and training missions. The fundamental purpose of NPCs is to serve Veterans by supporting VA research and education to improve the quality of care that Veterans receive.

Beyond administering research projects and education activities, NPCs support a variety of VA research infrastructure and administrative expenses. They have provided seed (funding for new investigators who are just starting out in research) and bridge (funding for personnel who are between funded projects) funding for investigators, staffed animal care facilities, funded recruitment of clinician researchers, paid for research administrative and compliance personnel, supported staff and training for institutional review boards and much more.

III. NPC LOCATIONS

VAMCs throughout the country have long recognized the benefit of establishing NPCs to help support the conduct of VA-approved research and education activities. During 2020, there were 80 NPCs located in 43 states, Puerto Rico and the District of Columbia. All of the NPCs filed annual reports. Of these 80 NPCs, there were 73 research and education NPCs and 7 research-only NPCs. As shown in Table 1 below, the NPCs vary greatly in size. Revenue indicates the funds received by the NPC:

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Revenues Range	# of NPCs (2020)	# of NPCs (2019)	# of NPCs (2018)	# of NPCs (2017)	# of NPCs (2016)	# of NPCs (2015)	
Below \$500K	20 (25%)	19 (23%)	22 (27%)	27 (33%)	22 (27%)	23 (28%)	
\$500K- \$1M	15 (19%)	14 (17%)	13 (16%)	12 (14%)	19 (23%)	14 (17%)	
\$1M- \$ 10M	39 (49%)	42 (53%)	41 (50%)	38 (46%)	36 (43%)	39 (47%)	
\$10M & Above	6 (7%)	6 (7%)	6 (7%)	6 (7%)	6 (7%)	7 (8%)	
Total NPCs	80	82	83	83	83	83	

<u>Note</u>: Tables and statistics presented in this summary report reflect national-level NPC data. Data at the level of each individual NPC is included in the (separate) Appendix.

IV. ANNUAL REPORTING

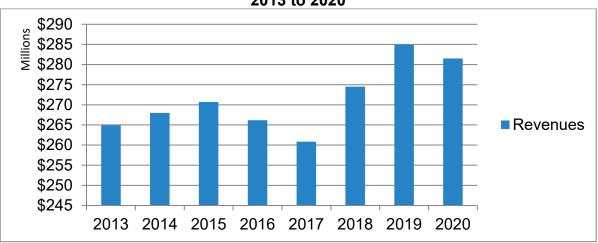
Under 38 U.S.C. § 7366(b), NPCs must submit to the Secretary of VA a detailed statement of their operations, activities and accomplishments during the previous year. Veterans Health Administration (VHA) *Handbook 1200.17, VA Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C., Sections 7361 through 7366,* dated April 27, 2016, requires each NPC to submit an Annual Report to VA's Chief Research and Development Officer on or before June 1 of each year. VA's Nonprofit Program Office (NPPO), located in VHA's Office of Research and Development (ORD), reviews the NPC Annual Reports and is responsible for summarizing the information for the NPC Annual Report to Congress. The information submitted by NPCs consists of, but is not limited to, Internal Revenue Service Form 990 – *Return of Organizations Exempt from Income Tax*, audited financial statements, the auditor's management letter (if applicable) and related revenue and expense information.

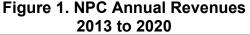
V. FINANCIAL REPORTING

Revenues

In June 2021, the NPCs reported \$281,523,798 in total revenues during the 2020 reporting period, including interest income and other miscellaneous receipts. This was nearly a record high for NPC revenues – a 1.2% decrease from the record amount recorded last year. Thirty-six NPCs reported an increase in overall revenues in 2020 compared to 43 in 2019, while 44 experienced declines.

From 2000 through 2007, total NPC revenue trended upward. In 2008 and 2009, revenues decreased. Revenues increased substantially in 2010 and 2011, were flat for 2012, but increased again in 2013, 2014 and 2015. Revenues for 2016 decreased by 1.7% and again decreased by 2.8% for 2017, but rebounded strongly in 2018, increasing by 5.3% and then by another 3.8% to the record high achieved in 2019. Figure 1 below illustrates the changes since 2013.





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Under the title 38 statutory reporting requirements, NPCs are required to report research and education revenues and expenditures separately. In addition, they must report revenues based on governmental or non-governmental (private) funding sources. Ninety-eight percent of total revenue was received in support of research, while less than one percent was received in support of education (see Figure 2). The remaining one percent was received from other sources such as interest income.

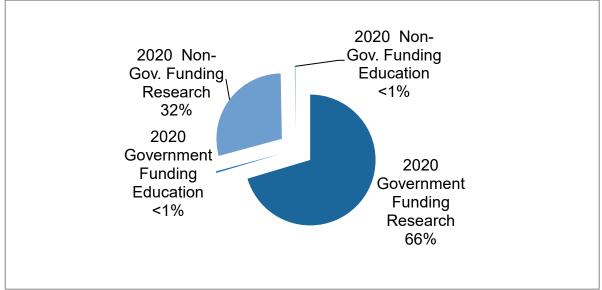


Figure 2. 2020 NPC Revenues by Funding Source

As in the previous year, revenue from governmental research and education sources comprised the largest component of funding received by NPCs (approximately 66%). In 2020, governmental funding increased by 4.2% to \$197 million, from the previous \$189 million in 2019.

Revenues from non-governmental sources decreased 11%, from \$91 million in 2019 to \$81 million in 2020. Other revenue sources (e.g., interest income) decreased by \$1.8 million to a total of \$2.9 million.

In 2020, the number of NPCs reporting revenue from governmental sources (including VA) was 67, the same as in 2019.

Funding Sources

NPCs continue to obtain funding from diverse sources, including private sector companies, charitable foundations, private individuals, state and local governments, universities and Federal entities such as the National Institutes of Health (NIH), Department of Defense (DoD) and Centers for Disease Control and Prevention (CDC).

Funds coming to NPCs from VA are either Intergovernmental Personnel Act (IPA) assignment agreement reimbursement funds or funds from another agency or private entity that have been passed through VA to NPCs.

NPCs are required to identify the funding sources for both governmental and nongovernmental amounts greater than \$25,000 (see Figure 3 below for the breakdown). For 2020, the total revenue received from these sources was \$249 million.

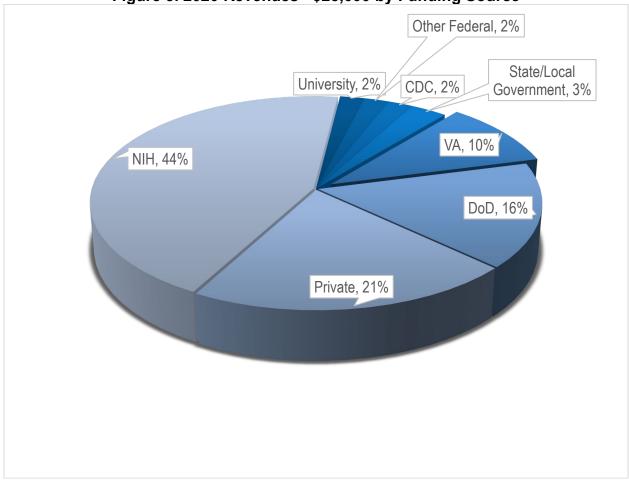


Figure 3. 2020 Revenues >\$25,000 by Funding Source

Expenses

In June 2021, NPCs reported expenses totaling \$282.3 million during 2020, an increase from 2019 expenses of \$276.2 million. These expenses financed research projects and their supporting infrastructure as well as salaries, equipment and other research and education-related costs. NPCs employed approximately 2,500 people, supported more than 2,100 principal investigators and administered approximately 3,700 research projects.

Because the statutory purpose of NPCs is to facilitate VA research and education, all funds spent must support those activities except for amounts that cover NPC administration. Figure 4 below highlights the expenses over the past 8 years. The expenses increase as the revenues increase.

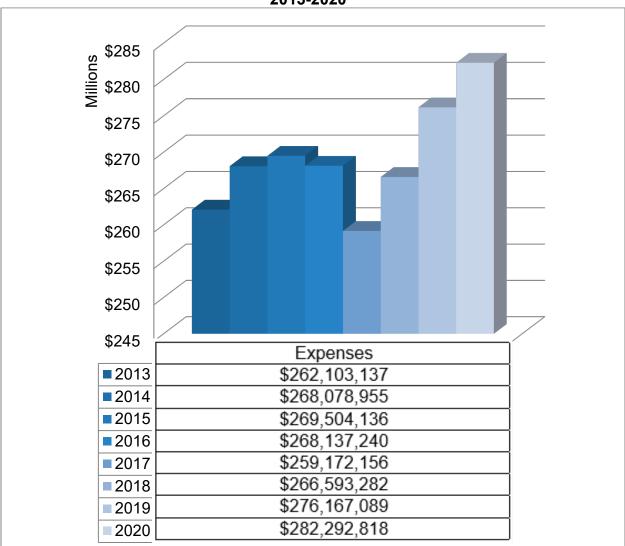


Figure 4. NPC Annual Expenses 2013-2020

During 2020, approximately 54% of total expenses covered salaries and benefits; approximately 1% of total expenses covered travel and the remaining 45% represented other expenses in direct support of VA research and education activities or NPC business operations.

NPCs continue to spend a relatively small amount on administrative expenses, averaging 16% (\$46 million) of total expenditures for 2020. Figure 5 below shows the average administrative and program expenses for NPCs over time. Administrative costs have remained relatively steady, increasing slightly from 14% to 16% between 2015 and 2018 but otherwise remaining essentially flat.

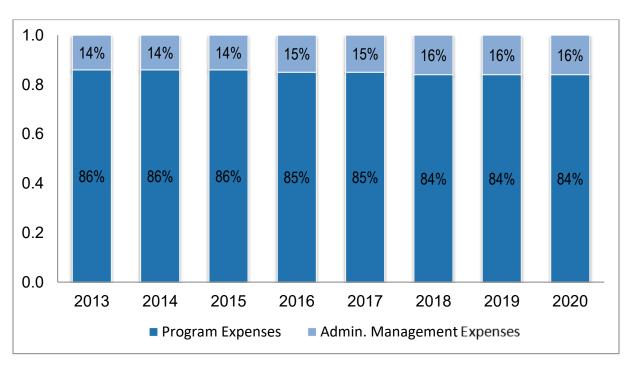


Figure 5. NPC Total Combined Administrative Management Expenses vs. Direct Program Expenses 2013-2020

Compensation Expense

During 2020, the NPCs reported total compensation expenses including benefits totaling \$153 million, a 0.6% decrease from 2019. The NPC salary expenditures supported a variety of personnel (including research technicians, pharmacists, scientists, nurses, physicians and administrative staff).

Of the \$153 million spent for compensation, 78% (\$119 million) was used to support personnel directly engaged in VA research. Approximately 22% (\$33 million) was expended for NPC administrative salaries and benefits. Slightly more than \$1 million, or less than 1%, was expended in support of staff involved in educational activities. Figure 6 below displays the breakdown of compensation expenses paid to NPC personnel.

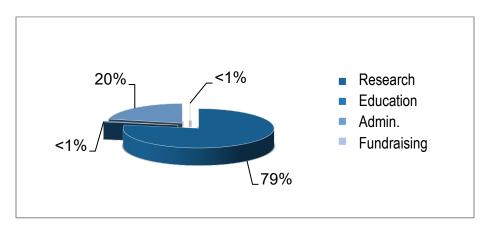


Figure 6. NPC 2020 Compensation Expenses by Category

Travel Expenses

NPCs support travel for VA and NPC personnel to attend scientific and educational meetings, seminars and conferences. VA benefits from such travel because it enhances the ability of VA staff to pursue research and education endeavors important to VA's health care, training and research missions. Sixty-eight NPCs reported travel expenditures totaling \$1.3 million for 2020, which was down sharply from the prior year (by \$2.7 million, or 68%). Approximately 75% of this expense in 2020 supported travel for personnel directly engaged in research or education activities. Figure 7 below shows the total travel expenses over the last eight years.¹

¹ See attachment for a breakdown of the amount expended by each corporation for travel conducted for research and the amount expended by each corporation for travel conducted for education.

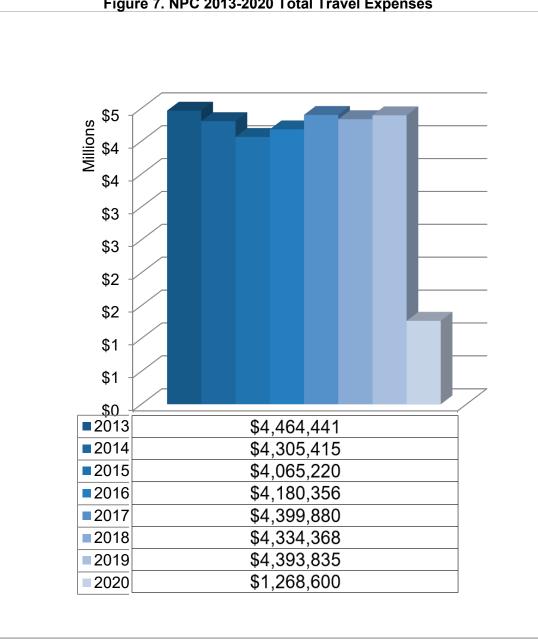


Figure 7. NPC 2013-2020 Total Travel Expenses

Other Expenses

While furthering VA's research and education missions, NPCs incur other costs in addition to payroll, benefits and travel. During the 2020 reporting period, other expenses totaled \$128 million, up by 8.5% from \$118 million in 2019. Other expenses included, but were not limited to, legal fees, insurance, accounting, auditing, consulting services (statisticians, information technology experts, etc.), supplies, postage, shipping,

equipment purchases, rentals and maintenance, printing, publications, utilities and conference registrations.

Payees

Each NPC hires employees and contracts with various vendors ("payees") to support VA-approved research and education activities.

The vendors provide products and services that sustain research, education and business operations. Any payee receiving more than \$50,000 per year is identified in the NPC report and is presented in Figure 8 below:

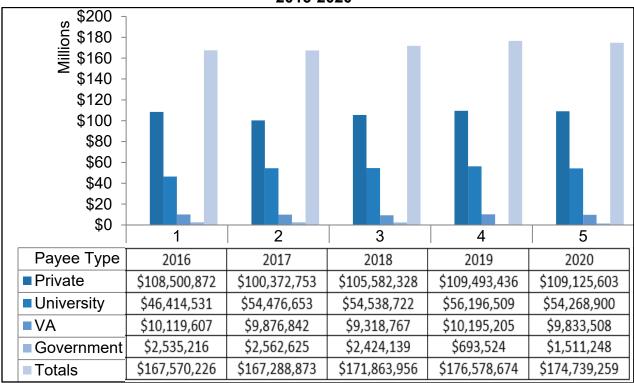


Figure 8. Chart of NPC Payees Greater than \$50,000 by Type 2016-2020

Figure 8 above lists the 4 major types of payees and provides the total amount paid to each type by year as well as the overall total amount paid to all payees. Below is some further description of each type of payee:

- <u>Private</u>: Private payees include employees, consultants, etc.
- <u>University</u>: State and private university payees may include reimbursements from grants or sub-awards.
- <u>VA</u>: VA reimbursements are costs reimbursed in support of VA research and education activities.

<u>Government</u>: Other governmental payees include sub-awards or pass-through funds to non-VA governmental entities.

Financial Position

NPCs reported a net worth totaling \$214.1 million at the end of 2020, which is nearly the same as at the end of 2019. Gross assets under management were roughly \$335 million, while liabilities were roughly \$121 million. It should be noted that in many cases the NPC's include funds that are obligated for the future performance of research projects in net worth. Although this is acceptable under U.S. generally accepted accounting principles, there is nonetheless an obligation to expend project funds counted as equity in order to accomplish research and education projects. Unencumbered net worth for all NPCs combined is estimated at \$63 million for 2020, up by 8.5% from the prior year.

The ratio of net worth to revenues was 76% for all NPCs. For the top 20 NPCs by revenues, which comprised 75% of total revenues, the net worth ratio was 59%. Some large NPCs that rely heavily upon awards from NIH, DoD and other Federal agencies, had substantially lower net worth ratios than the average and have been advised to conserve their net worth as best they can and to augment it when possible.

VI. PROJECTS, ACTIVITIES AND ACCOMPLISHMENTS

VA researchers conducted a variety of projects during the 2020 reporting period, and NPCs facilitated these projects. Many of these research projects were clinical trial studies that focused on the treatment of medical conditions prevalent in the Veteran population. Such studies benefit Veterans by providing them access to innovative, cutting-edge pharmaceuticals and medical devices. Many Veterans who participate in VA clinical trial studies benefit from both the "hands on" care provided and the interaction between VA, NPC staff and other participants.

In support of VA's research programs, in September 2012, VA's Office of General Counsel established a new team called the Specialty Team Advising Research (STAR). This is a small group of VA attorneys who address the needs of the NPCs in their role supporting VA's approved research and education programs. STAR advises on many topics, including review and approval of various research agreements such as Cooperative Research and Development Agreements, nondisclosure agreements, subawards and various partnerships. Having this small but highly capable team of legal specialists has greatly helped VA's research programs and supported NPC growth.

The quality of care given to Veterans enrolled in clinical studies is exceptional and is a direct result of the close one-on-one relationships between the experienced medical professional conducting research and the Veterans. VAMCs may potentially benefit from drugs and devices donated by sponsoring institutions and pharmaceutical companies as well as from NPC salary support for nurses and physicians caring for Veteran patients enrolled in clinical trial studies.

NPCs also support VA in many ways beyond administering funds. Several examples are listed below:

• Renovating and upgrading VA research infrastructure;

- Providing funds, staffing and training support to VA and affiliate universities to help cover Institutional Review Board requirements;
- Paying for expenses related to recruitment of research investigators to VA;
- Funding seed grants to new investigators to aid them in establishing their VA research careers;
- Employing support staff for VA research projects;
- Covering the cost of training VA research personnel on topics such as research compliance, good clinical practice and board governance;
- Underwriting bridge funding for VA investigators who are between research grant awards;
- Supporting travel and registration fees for VA investigators to attend scientific conferences;
- Procuring personnel, equipment and supplies for VA animal research facilities;
- Providing funds for research pharmacy staff and equipment; and
- Hosting national educational conferences for VA personnel with incidental attendance by health care professionals from surrounding communities.

VII. CONFLICTS OF INTEREST

NPC directors, officers and employees are subject to the conflict-of-interest policy adopted by that NPC. NPC employees who also hold VA appointments are subject to the Federal conflict of ethics laws and regulations. If at any time there is a conflict with NPC policy, the Federal conflict of interest laws and regulations take precedence.

VIII. VA NONPROFIT PROGRAM OVERSIGHT BOARD

In 2004, VA senior leadership created the VA Nonprofit Program Oversight Board (Board) to serve as VA's senior management oversight body over NPC activities and programs. The Board meets on a quarterly basis to review the activities of the NPCs for consistency with VA policy and interests. The Board may also make recommendations to the Secretary and Under Secretary for Health (USH) concerning changes to and implementation of VA policy regarding NPCs. Board membership is limited to VA employees and includes the following individuals:

- USH, or designee;
- General Counsel, or designee;
- Assistant Deputy USH for Operations and Management;
- Chief Research and Development Officer;
- Chief Academic Affiliations Officer;
- Chief Financial Officer for VHA, or designee;
- Member, Office of Research and Development Field Research Advisory Committee;
- Field Associate Chiefs of Staff Research from VAMCs; and
- Field Designated Education Officers from VAMCs.

IX. INDEPENDENT AUDIT REPORTS

VA NPPO reviews the independent audit reports and related NPC audited financial statements for the NPCs. NPPO also reviews other documents such as the independent audit management letters; lists of program activities and accomplishments; and supplemental revenue and expenditure information. This oversight is performed to obtain substantive evidence of accountability and to provide a balanced picture of NPC program activity.

Any material weaknesses or significant deficiencies in internal controls and related recommendations made by NPCs' independent auditors are noted. NPPO tracks these from year to year to determine whether the NPCs have taken the appropriate corrective actions as recommended by their independent audits.

Under 38 U.S.C. § 7366(b) each NPC with annual revenues more than \$500,000 for the year is required to obtain an independent external audit of its financial statements for the year. NPCs with annual revenues between \$100,000 and \$500,000 must obtain independent external audits every 3 years. For those NPCs with \$100,000 or less in annual revenues, an independent external audit is not required. For 2020, 14 NPCs were not required to obtain an independent audit. Of the 80 NPCs, 66 (or 82.5%) submitted audited financial statements. For 2020, 98% of total NPC revenues and 99% of total expenses were subject to independent external audits.

There are three ascending levels of independent audits:

- (1) Generally Accepted Auditing Standards (GAAS) in the United States of America Audit: This audit requires the auditor to plan and perform the audit to obtain reasonable assurance that the financial statements are free of material misstatements. The auditor assesses internal controls, management and governance. An NPC receiving more than \$100,000 but less than \$500,000 in funding is required to obtain, at a minimum, an audit in accordance with GAAS once every 3 years.
- (2) Generally Accepted Government Accounting Standards (GAGAS) Audit: This audit obtains reasonable assurance that the financial statements are free of material misstatements. The GAGAS audit is used when required by provisions of laws, regulations, contracts and grants.
- (3) Uniform Guidance or Single Audit: This audit is performed in accordance with Office of Management and Budget-published rules and regulations, when annual expenditures are from Federal funds exceeding \$750,000. The uniform guidance audit is designed to provide assurance that the financial statements are reasonable and there is compliance with the legal and regulatory requirements of the Federal contract(s) and grant(s) and with sound internal controls.

Ten NPCs were cited by their auditors for material weaknesses. In two of these NPCs, there were repeat material weaknesses from the prior year. NPCs with material weaknesses are working closely with NPPO and their external auditors to ensure correction of the weaknesses prior to the next audit.

NPPO requires an in-depth action plan from each NPC with material weaknesses, significant deficiencies and auditor recommendations. These audit action items are followed up on by email and during periodic on-site reviews.

All but three NPCs reporting material weaknesses were audited under the uniform guidance provisions. As noted above, NPPO will follow up to ensure these material weaknesses and other deficiencies are corrected.

The Executive Director (ED) of each NPC is responsible for providing a copy of the auditor's report to the NPC Board of Directors and involving the Board directly in the resolution of any deficiencies. NPPO has requested a remediation action plan from these NPCs.

X. NPPO OVERSIGHT PLAN AND RESULTS

NPPO is charged with conducting oversight for the 80 VA-affiliated NPCs nationwide. NPPO reviews the Operations Oversight Questionnaire and the Internal Control Questionnaire that is provided in advance of the on-site visit with the ED. NPPO routinely tests samples of various transactions and accounting records, such as policies and procedures, cash disbursements, credit card purchases, bank statements and reconciliations, payrolls and IPA assignment agreements.

The limited on-site reviews by NPPO are for the purpose of providing audit, investigative and oversight-related services that do not involve a GAGAS full financial, attestation or performance audit examination. NPPO's limited reviews are performance audits that emphasize compliance with VA policy and conformity to sound business practices and accepted internal control standards. NPPO's limited reviews are not designed to detect fraud, waste, abuse or other irregularities. NPPO's reviews are substantially narrower in scope than a financial audit examination. The objective of a financial audit examination is the expression of an opinion on the subject matter, and, accordingly, no such opinions are expressed as part of NPPO reviews. *Ref. <u>Government Auditing Standards 2011 Revision</u>, <i>Chapters 2.12 and 5.56, Pages 19 and 116*. Nonetheless, NPPO reserves the rights to extend its limited reviews; initiate other reviews or investigations; and arrange for the conduct of complete GAGAS financial, attestation or performance audits if needed for effective VHA oversight. NPPO observes auditing standards set by the Comptroller General of the United States.

- (1) All NPCs will be reviewed triennially regardless of financial condition. To accomplish this, one-third of the NPCs are audited each year.
- (2) More frequent or off-cycle on-site reviews may be scheduled at the discretion of the NPPO Board or the NPPO Director, as they are deemed necessary or desirable.
- (3) NPCs with identified operating problems or serious internal control weaknesses will be reviewed on-site annually or more often, if necessary, and monitored. Once the issues are resolved and the NPC receives a satisfactory review, its review schedule will generally be moved back to the triennial schedule.

- (4) New EDs are welcomed and notified of the next ED workshop and the availability of the NPPO website. They are also given NPPO staff contact information within the first 45 days of employment.
- (5) NPCs that are starting-up, reactivating, merging or deactivating will be visited as needed.
- (6) NPCs with reported irregularities (e.g., by whistleblowers) will be reviewed onsite as soon as practicable and have appropriate follow-up action taken.
- (7) NPCs requesting on-site visits to resolve internal control, financial systems or financial management problems will be visited as soon as possible.

All 80 NPCs were reviewed by NPPO in the first 3 triennial periods – fiscal year (FY) 2011 through 2013, FY 2014 through 2016 and FY 2017 through 2019. NPPO is pleased to report that there was a trend of much improved on-site review results in the last 3 years of audits conducted in FY 2017 through 2019. Wherever there are prior required actions, NPPO always follows up on them in the subsequent review.

The on-site audits were necessarily postponed in March 2020 with the advent of the pandemic but were resumed in late August 2020.

Results for the 3 completed triennial review periods were as follows:

First triennial period, FY 2011–2013:

- 585 required actions
- 219 consultative suggestions
- 14 perfect reviews

Second triennial period, FY 2014–2016:

- 46 prior required actions
- 567 new required actions
- 92% success rate for implementing prior required actions
- 153 consultative suggestions
- 13 perfect reviews

Third triennial review period, FY 2017–2019:

- 27 prior required actions
- 270 new required actions (less than half of previous period)
- 95% success rate for implementing prior required actions
- 142 consultative suggestions
- 44 perfect reviews

NPPO developed and implemented ED and Financial Manager training classes, held in Kansas City, Missouri late in the second triennial period. Largely, because of these trainings, on-site review results greatly improved in the third triennial period.

Formal review reports are prepared for each NPPO on-site review and discussed with the NPC EDs and Medical Center Directors and their key staff while on site.

Additionally, the NPCs' written responses to the review reports are incorporated into the reports before they are forwarded to the VHA Chief Financial Officer's office.

In addition to the routine triennial reviews, NPPO has performed non-routine whistleblower complaint, timekeeping and fraud investigations. NPPO has also performed several on-site management consulting engagements.

Other routine oversight conducted at NPPO include reviews of the following:

- (1) Annual reports due June 1 on forms prescribed by NPPO;
- (2) Annual audited financial statements due to NPPO by June 1;
- (3) Annual Form 990 income tax returns due to NPPO by June 1;
- (4) Remediation plans for all NPCs with material weaknesses reported by their independent auditors;
- (5) Remediation plans for all NPCs with significant deficiencies and auditor recommendations;
- (6) Monthly financial statements compared to budget and last year for NPCs with identified operating problems and/or inadequate reserves; and
- (7) Immediate attention to all NPC requests for assistance or advice.

VA Office of Inspector General (OIG) investigated 7 NPCs in the past 2 years. As a result of these audits, VAOIG made appropriate recommendations to VHA for oversight improvements. NPPO is leading the implementation of these VAOIG recommendations.

XI. NPPO TRAINING

NPPO has been engaged in training the NPC Boards of Directors and other personnel by:

- (1) Providing a 1/2-hour presentation on board governance during each on-site review.
- (2) Developing and facilitating a 2-day workshop for EDs.
- (3) Developing and initiating a 2-day workshop for NPC top level financial managers.
- (4) Developing training courses for VA's Talent Management System for mandatory topics (i.e., "Internal Controls" and "Conflict of Interest")
- (5) Maintaining an easy-to-navigate, user friendly and informative website.
- (6) Developing PowerPoint trainings covering proper completion of IPA assignment agreements and preparation for NPPO on-site reviews.

XII. CONCLUSION

VA-affiliated NPCs continue to make a substantial contribution to VA research and education missions. The 2020 NPC Annual Report to Congress demonstrates that NPCs are fulfilling their Congressional mandate in a responsible and conscientious manner.

Expertise in NPC governance and management is improving as evidenced in the on-site reviews and the NPC annual reporting to VA. VA-affiliated NPCs contribute significantly to the success of VA's research and education programs.

This report and NPPO's on-site reviews illustrate that NPCs are a highly efficient means to maximize the benefits to VA of supporting externally funded research conducted in VA facilities. NPCs greatly facilitate research and education that benefit Veterans. Additionally, NPCs foster vibrant research environments at VAMCs, enhancing VA's ability to recruit and retain clinician-investigators and other talented personnel who apply their knowledge to state-of-the-art care for Veterans.

Department of Veterans Affairs December 2021